K111548

FUJIFILM
Fujifilm Medical Systems, USA

AUG 30 2011

510(k) Summary
Wireless/Wired FDR D-EVO Flat Panel Detector System (DR-ID600 w/DR-ID611SE)

Date: June 1, 2011

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, CT, 06902, USA

Contact Person:

Name: Katherine Y. Choi, RAC
Title: Regulatory Affairs Specialist
Telephone: (203) 602-3568
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Identification of the Proposed Device:

Proprietary/Trade Name:	Wireless/Wired FDR D-EVO Flat Panel Detector System (DR-ID600 w/DR-ID611SE)
Classification Name:	Solid State X-ray Imager (Flat Panel/Digital Imager)
Regulations Number:	21 CFR 892.1650
Product Codes:	90 MQB
Device Class:	Class II
Review Panel:	Radiology
Common Name:	Flat Panel Digital Detector

I. INDICATIONS FOR USE

The Wireless/Wired FDR D-EVO flat panel detector system is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications wherever conventional film/screen or CR systems may be used. The FDR D-EVO is not intended for mammography, fluoroscopy, tomography, and angiography applications.

II. DEVICE DESCRIPTION

The proposed device, DR-ID600 w/DR-ID611SE is a modified version of our currently-cleared predicate device, Wireless/Wired FDR D-EVO flat panel detector system (DR-ID600 w/DR-ID601SE), K103596. The predicate device includes the 14x17" flat panel detector model DR-ID601SE using GOS (Gadolinium Oxysulfide) scintillator whereas the proposed device introduces the 14x17" flat panel detector model DR-ID611SE using a different scintillator material, CsI (Cesium Iodide).

FUJIFILM's unique Irradiated Side Sampling (ISS) design delivering high image quality, and wireless communication specifications remains unchanged in the proposed device.

The proposed DR-ID600 w/DR-ID611SE is a portable digital detector system that acquires and digitizes x-ray exposures from standard radiographic systems, which is the same as our legally marketed predicate device, DR-ID600 w/DR-ID601SE. The proposed device is designed to be used in any environment that would typically use a radiographic cassette. It can be placed in a wall bucky for upright exams, a table bucky for recumbent exams, or removed from the bucky for non-grid exams. All of which are also the same as our legally marketed predicate device.

III. SUMMARY OF STUDIES

The proposed device, DR-ID600 w/DR-ID611SE successfully completed internal and international IEC testing requirements. In addition, the FDA *Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices,* issued on August 6, 1999 was followed to describe the detector characteristics.

FUJIFILM performed an image quality reader study on 30 image pairs comparing the images obtained between the proposed CsI detector (DR-ID611SE) and our legally marketed GOS detector (DR-ID601SE). Three board-certified radiologists reviewed the images and all images were deemed to be of diagnostic capability. In addition, the consensus results of the three radiologists shows that the proposed device provides images of equivalent or better diagnostic capability to those of our cleared predicate device (K103596) by 93.3%. Test protocol summary and analysis results are enclosed in the submission.

IV. SUBSTANTIAL EQUIVALENCE

The proposed device, DR-ID600 w/DR-ID611SE is substantially equivalent to the following legally marketed devices.

Legally Marketed Device	510(k) #
Wireless/Wired FDR D-EVO flat panel detector system (DR-ID600 w/DR-ID601SE)	K103596
Canon CXDI-70C Wireless	K102012

The proposed DR-ID600 w/DR-ID611SE has the same Indications for Use and very similar functional and technical requirements as our currently-cleared predicate device, K103596. The proposed device's wireless communication specifications remain unchanged as K103596. In addition, the scintillator material used in the proposed device is the same material as the legally marketed device, K102012.

V. CONCLUSION

The proposed DR-ID600 w/DR-ID611SE is substantially equivalent to the legally marketed devices and conforms to applicable medical device safety standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Katherine Y. Choi, RAC
Regulatory Affairs Specialist
Fuji Medical Systems U.S.A., Inc.
419 West Avenue
STAMFORD CT 06902

AUG 23 2013

Re: K111548
Trade/Device Name: Wireless/Wired FDR D-EVO Flat Panel Detector System (DR-ID600 w/DR-ID611SE)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: July 26, 2011
Received: July 27, 2011

Dear Ms. Choi:

This letter corrects our substantially equivalent letter of August 30, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111548

Device Name: Wireless/Wired FDR D-EVO Flat Panel Detector System (DR-ID600 w/DR-ID611SE)

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 111548